



CLIA Categorization at the FDA: 6 Month Report

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Microbiology Devices Panel Meeting, June 28, 2000

CLIA '88

History

- ▶ Transferred from CDC on January 31, 2000
- ▶ FDA responsible for the categorization of commercially marketed test systems

Current Status

- DCLD CLIA Team
- Partners in CLIA
- CLIA '88
- Waived Tests
- Progress Report
- New Technology
- CLIA Waiver Workshop

CLIA '88

Future Directions

- ▶ Many paths forward
- ▶ Direction unclear

History

- ▶ Transferred from CDC on January 31, 2000
- ▶ FDA responsible for the categorization of commercially marketed test systems
- ▶ One stop shopping, clearance and categorization
- ▶ CDC responsible for categorization of laboratory procedures
 - e.g. provider performed microscopy
- ▶ Interagency agreement with HCFA

CLIA Team in DCCLD

Chemistry/Toxicology

- ▶ Miin-Rong Tsai
- ▶ Arleen Pinkos
- ▶ Carol Benson
- ▶ John Hyde
- ▶ Jim Callaghan

Hematology/Pathology/Immunology

- ▶ Louise Magruder
- ▶ Deborah Moore
- ▶ Josie Bautista
- ▶ Maria Chan
- ▶ Michelle Clark-Stuart

CLIA Team in DCCLD

Microbiology

- ▶ Marian Heyliger
- ▶ Liz Rogers
- ▶ Kathy Wright

Steve Gutman, Director and Staff

- ▶ Clara A. Sliva, Acting CLIA Coordinator
- ▶ Joe Hackett, Associate Director
- ▶ Kaiser J. Aziz, Associate Director
- ▶ Don St. Pierre, Deputy Director

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- ▶ Candy Cheung, Systems Analyst
 - ▶ Marina Kondratovich, Statistician

Partners in CLIA Categorization

Health Care Financing

- ▶ Notified of waiver approval
- ▶ Provided with cleared, approved package insert

Centers for Disease Control and Prevention

- ▶ Consulted on waiver applications
- ▶ Kept apprised on new technology

Clinical Laboratory Improvement Amendments of 1988 (CLIA)

Law specified that laboratory requirements be based on complexity of the test performed

- ▶ February 28, 1992 regulations published to implement CLIA (42 CFR part 493)
- ▶ 3 complexity categories; high, moderate, waived
- ▶ Waived tests defined as cleared by FDA for “home use”; and
- ▶ Waived tests defined as simple and accurate as to render likelihood of erroneous results negligible

Clinical Laboratory Improvement Amendments of 1988 (CLIA)

- ▶ September 13, 1995 proposed criteria for waiver published as Notice of Proposed Rulemaking
- ▶ In November 1997, CLIA waiver provisions revised by Congress
 - tests approved by FDA for home use are automatically waived
 - simple, accurate to render chance of erroneous results, by the user negligible
 - no reasonable risk of harm if performed incorrectly

Waived Test Systems

- ▶ Source of some controversy
- ▶ Waiver allows lab to perform the test without having to meet national personnel, quality assurance, and proficiency testing standards

Waived Test Systems -OTC

- ▶ FDA considers whether they are sufficiently simple and reliable that they may be performed by patients themselves or by untrained family members.
- ▶ FDA also considers whether the health benefits to be gained by the use of such devices outweigh the risks.

Waived Test Systems -OTC

- ▶ A growing number of lab tests have been cleared by the FDA for over-the-counter (OTC) and prescription home use.
- ▶ For example, glucose, cholesterol, HDL cholesterol, triglycerides and prothrombin time.
- ▶ This list is expected to substantially expand in the next few years.

CLIA Waiver Workshop

Time is right to revisit the criteria for waiver

- ▶ Proposed rule published by CDC on September 13, 1995
- ▶ FDA needs to finalize to implement its responsibility for CLIA waiver
- ▶ Beneficial to all groups
- ▶ Interest in waived tests is high

CLIA Waiver Workshop

Interested parties

- ▶ Consumers
- ▶ Medical Community
- ▶ Laboratorians
- ▶ Industry

Meets: August 14-15, 2000

Washingtonian Marriott Hotel, Gaithersburg, MD

www.fda.gov/cdrh/clia

New Technology

- ▶ Waiver tests, simple to perform
- ▶ But may be driven by complex technology
- ▶ Industry has proven the technology is reliable

Performance: CLIA Categorization

Type of categorization	Reviews Completed 6 months FY00	Average Total Time (days)
Moderate	620	64
High	100	64
Waived	90	83

Future Directions

- ▶ Expand the test list?
- ▶ Limit the test list?
- ▶ Damn near perfect test?